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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q85454

Andrew David BACON, et al.

Appln. No.: 10/520,169

Group Art Unit: Unassigned

Confirmation No.: Unassigned

Examiner: Unassigned

Filed: January 4, 2005

For: METHOD TO ENHANCE AN IMMUNE RESPONSE OF NUCLEIC ACID  
VACCINATION

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

1. L. Alvarez-Lajonchere et al., "Additives and Protein-DNA Combinations Modulated the Humoral Immune Response Elicited by a Hepatitis C Virus Core-encoding Plasmid in Mice", *Mem Inst Oswaldo Cruz*, Rio de Janeiro, Vol. 97, No. 1, January 2002, pp. 95-99.
2. G. Gregoriadis et al., "High Yield Incorporation of Plasmid DNA within Liposomes: Effect on DNA Integrity and Transfection Efficiency", *Journal of Drug Targeting*, Vol. 3, 1996, pp. 469-475.
3. G. Gregoriadis et al., "Vaccine Entrapment in Liposomes", *Methods*, Vol. 19, 1999, pp. 156-162. This reference was previously listed on a PTO/SB/08 A & B filed January 4, 2005. However, for the Examiner's convenience, a copy is enclosed herewith.

BACON et al.  
U.S. Appln. No.: 10/520,169  
INFORMATION DISCLOSURE STATEMENT

4. M. Gürsel et al., "Immunoadjuvant action of plasmid DNA in liposomes", *Vaccine*, Vol. 17, 1999, pp. 1376-1383.
5. C. Kirby et al., "Dehydration-Rehydration vesicles: A Simple Method for High Yield Drug Entrapment in Liposomes", *Biotechnology*, November 1984, pp. 465-472.
6. D.M. Klinman et al., „CpG motifs as immune adjuvants“, *Vaccine*, Vol. 17, 1999, pp. 19-25.
7. A. Lanzavecchia, "Antigen-specific interaction between T and B cells", *Nature*, Vol. 314, April 11, 1985, pp. 537-539.
8. J. Senior et al., "Dehydration-rehydration vesicle methodology facilitates a novel approach to antibody binding to liposomes", *Biochimica et Biophysica Acta*, Vol. 1003, 1989, pp. 58-62.
9. B. Zadi et al., "A Novel Method for high-Yield Entrapment of Solutes into Small Liposomes", *Journal of Liposome Research*, Vol. 10, No. 1, 2000, pp. 73-80.
10. WO 97/28818 published August 14, 1997, to Therexsys Limited. This reference was previously listed on a PTO/SB/08 A & B filed January 4, 2005. However, for the Examiner's convenience, a copy is enclosed herewith.
11. WO 98/10748 published March 19, 1998, to The School of Pharmacy, University of London. This reference was previously listed on a PTO/SB/08 A & B filed January 4, 2005. However, for the Examiner's convenience, a copy is enclosed herewith.
12. WO 99/30733 published June 24, 1999, to Smithkline Beecham Biologicals S.A. This reference was previously listed on a PTO/SB/08 A & B filed January 4, 2005. However, for the Examiner's convenience, a copy is enclosed herewith.
13. WO 01/41739 A2 published June 14, 2001, to Lipoxen Limited.
14. WO 01/56548 A2 published August 9, 2001, to Lipoxen Technologies Limited.
15. U.S. Patent No. 5,459,127 issued October 17, 1995, to Felgner et al.
16. U.S. Patent No. 6,030,619 issued February 29, 2000, to Granoff et al.

One copy of each of the listed documents, except for the two U.S. Patents, is submitted herewith.

BACON et al.  
U.S. Appln. No.: 10/520,169  
INFORMATION DISCLOSURE STATEMENT

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under § 1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

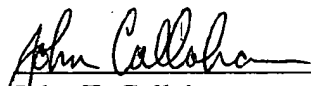
Respectfully submitted,

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**23373**

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Date: April 27, 2005

Substitute for Form 1449 A &amp; B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/520,169
Confirmation Number	Unassigned
Filing Date	January 4, 2005
First Named Inventor	Andrew David BACON
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	Q85454

Sheet	1	of	1
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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>3</sup> (if known)		
		US 5,459,127	A	10-17-1995	Felgner et al.
		US 6,030,619	A	02-29-2000	Granoff et al.
		US			
		US			
		US			
		US			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		WO	01/41739	A2	06-14-2001	Lipoxen Limited	
		WO	01/56548	A2	08-09-2001	Lipoxen Technologies Limited	

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		L. Alvarez-Lajonchere et al., "Additives and Protein-DNA Combinations Modulated the Humoral Immune Response Elicited by a Hepatitis C Virus Core-encoding Plasmid in Mice", <i>Mem Inst Oswaldo Cruz</i> , Rio de Janeiro, Vol. 97, No. 1, January 2002, pp. 95-99	
		G. Gregoriadis et al., "High Yield Incorporation of Plasmid DNA within Liposomes: Effect on DNA Integrity and Transfection Efficiency", <i>Journal of Drug Targeting</i> , Vol. 3, 1996, pp. 469-475	
		M. Gürsel et al., "Immunoadjuvant action of plasmid DNA in liposomes", <i>Vaccine</i> , Vol. 17, 1999, pp. 1376-1383	
		C. Kirby et al., "Dehydration-Rehydration vesicles: A Simple Method for High Yield Drug Entrapment in Liposomes", <i>Biotechnology</i> , November 1984, pp. 465-472	
		D.M. Klinman et al., "CpG motifs as immune adjuvants", <i>Vaccine</i> , Vol. 17, 1999, pp. 19-25	
		A. Lanzavecchia, "Antigen-specific interaction between T and B cells", <i>Nature</i> , Vol. 314, April 11, 1985, pp. 537-539	
		J. Senior et al., "Dehydration-rehydration vesicle methodology facilitates a novel approach to antibody binding to liposomes", <i>Biochimica et Biophysica Acta</i> , Vol. 1003, 1989, pp. 58-62	
		B. Zadi et al., "A Novel Method for high-Yield Entrapment of Solutes into Small Liposomes", <i>Journal of Liposome Research</i> , Vol. 10, No. 1, 2000, pp. 73-80	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.